



Food and Drug Administration



Center for Devices and Radiological Health

**Global Unique Device Identification Database (GUDID)
User Manual**

Version 1.0

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1 Introduction

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, the nation's food supply, cosmetics, dietary supplements, and products that give off radiation; and for regulating tobacco products.

Section 226 of the FDA Amendments Act (FDAAA) of 2007 and Section 614 of the FDA Safety and Innovation Act (FDASIA) of 2012 amended the Federal Food, Drug, and Cosmetic Act to add section 519(f), which directs FDA to promulgate regulations establishing a unique device identification system for medical devices along with implementation timeframes for certain medical devices. The Unique Device Identifier (UDI) Proposed Rule was published on July 10, 2012, followed by an amendment, published on November 19, 2012, modifying the implementation time frame for certain devices. In developing the proposed rule, FDA solicited input from a variety of stakeholders (e.g., manufacturers, global regulatory bodies, the clinical community, patient advocates) to ensure that as many perspectives were incorporated as possible. The UDI Final Rule was published on September 2013. Over the past year, FDA has been working on the design and development of the Global Unique Device Identification Database (GUDID).

This document is intended primarily to provide information about submitting data to the database for device Labelers¹, entities that will be responsible for providing the data to the GUDID. Please note that database enhancements will continue, to improve user experience, build in better validation rules, and make other necessary changes as we “learn” from the initial roll-out and implementation. The FDA intends to periodically update this document to reflect system changes and enhancements.

FDA's Guidance documents, other Technical documents and FAQs, including this technical document, do not establish legally enforceable responsibilities.

¹ The UDI Final Rule (<http://www.fda.gov/udi>) defines labeler as “any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and, any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler.”

2 How to obtain a GUDID Account

In order to submit data to GUDID, first an Organization account needs to be established. In order to do so, please refer to [Global Unique Device Identification Database \(GUDID\) - Draft Guidance for Industry \(PDF - 3.6 MB\)](#) . Visit www.fda.gov/udi to obtain an organization account.

3 Getting Started

3.1 Browser Compatibility

GUDID currently supports the following browsers:

- Internet Explorer 9 and 10
- Mozilla FireFox 17-22

Troubleshooting Internet Explorer Issues

If you are using Internet Explorer (IE) 9 or 10 and see the following message, Follow the instructions below to troubleshoot.

Warning!
Your web browser is not supported for this GUDID release. Please use a supported browser which is available under the About link. Sorry for any inconvenience

Text: Warning! Your web browser is not supported for this GUDID release. Please use a supported browser which is available under the About link. Sorry for any inconvenience.

Turn off Compatibility View in Internet Explorer 9 and 10


1. Open GUDID in Internet Explorer.
2. See if the Compatibility View button appears in the Address bar. (If you don't see the button, there's no need to turn off Compatibility View.)

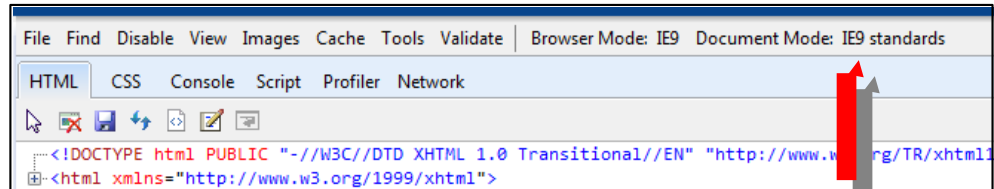


3. Tap or click the Compatibility View button to turn off Compatibility View.
4. The Compatibility View button should now appear grayed out:



Change Mode and Document version

1. Open GUDID in Internet Explorer.
2. Click F12 on the keyboard, or click the  icon in the right hand corner and click on Developer Tools.
3. In the top toolbar set the Browser Mode to IE9/IE10 and the Document Mode to IE9 standards/IE10 standards.



3.2. Common Functions

Main Page

URL: <https://gudid.fda.gov/gudid>

The *Main Page* is displayed as shown below. From this page you can login, search, among other functions as described in this document.



Login Screen

From the GUDID log in screen, enter your username and password for account management or data entry. Please review the System User Agreement prior to logging into the GUDID. At the first login, you must change your password.



Note to system users: When the Search functionality is enabled; the search capabilities will be available as a front-end Public Portal to the GUDID. No login information will be required. This public search will be restricted to non-proprietary data.

GUDID Global Unique Device Identification Database

About User Guide Login

GUDID Logo Menu Options

Search

GUDID Login

Login Panel

Username:

Password:

[Forgot Username/ Password](#)

Password must be 8-32 characters with at least one upper case letter, one lower case letter, one number and one of the following special characters [!, @, #, \$, %, &, '+, ~].

I agree to System User Agreement

Login

... WARNING ... WARNING ... WARNING ... WARNING ... WARNING ...

This information system is provided for U.S. Government-authorized use only.

[System User Agreement](#)

You are accessing a U.S. Government information system, the Global Unique Device Identification Database. The information system includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network.

Any unauthorized or improper usage of this information system is prohibited and may result in disciplinary action as well as civil and criminal penalties.

By using this information system, you understand and consent to the following:

- Anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. See Title 18 U.S.C. 1001.
- Any information system usage may be monitored, recorded, and subject to audit. Anyone using this information system expressly consents to monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.
- You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, and for any lawful government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system.
- Any communications or data transiting or stored in this information system may be disclosed or used for any lawful government purpose.

Username and Password

To retrieve a forgotten username, click **Forgot Username**. Enter email address associated with the username, and then click **Send MyUsername**. You will receive an email with the username. If you have more than one account linked to your email, you will receive an email for each username in GUDID. Note: This function does not reset the password.

GUDID Login

 Search function is temporarily disabled and will be enabled at a future date when the database is populated

Username:

Password:

[Forgot Username](#) [Password](#)

Password must be 8-32 characters with at least one upper case letter, one lower case letter, one number and one of the following special characters ['!', '@', '#', '\$', '%', '&', '+', '~'].

I agree to System User Agreement

Login

--- WARNING -- WARNING -- WARNING -- WARNING -- WARNING ---
This information system is provided for U.S. Government-authorized use only.

System User Agreement

You are accessing a U.S. Government information system, the Global Unique Device Identification Database. The information system includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network.

Any unauthorized or improper usage of this information system is prohibited and may result in disciplinary action as well as civil and criminal penalties.

By using this information system, you understand and consent to the following:

- Anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. See Title 18 U.S.C. 1001.

- Any information system usage may be monitored, recorded, and subject to audit. Anyone using this information system expressly consents to monitoring and is advised that if such monitoring occurs,

Search ▾

Retrieve Username

* required fields

 Search function is temporarily disabled and will be enabled at a future date when the database is populated

Email: *

Send My Username

Cancel

If you forget your password, click **Password**. Enter username and email associated with the password. Click **Send My Password**.

Search ▾

Retrieve Password

Search function is temporarily disabled and will be enabled at a future date when the database is populated

Username: *

Email: *

Send My Password

Cancel

You will receive two emails: 1) Password reset notification; 2) Temporary password. Login to the GUDID with the temporary password and your username. The system will then ask you to change your password.

User Profile for ██████████

required fields

You must change your password.

User Details

Change Password

When changing your password it must be 8-32 characters with at least one upper case letter, one lower case letter, one number and one of the following special characters [!, @, #, \$, %, &, +, ~].

Username: *

Current Password: *

New Password: *

Confirm Password: *

Change Password

You must change your temporary password to access GUDID functions. Enter the temporary password, a new password, and confirm your new password.

View and Edit User Profile To view the **User Profile**, click on the dropdown menu next to the username and role in the right hand corner. On the **User Profile** screen, you can make updates

and save changes by clicking **Save** on the *User Detail* tab, or Change your password on the *Change Password* tab.

Coordinator:

The screenshot shows the GUDID (Global Unique Device Identification Database) interface. At the top, there's a blue header with the GUDID logo and navigation links: About, User Guide, and Logout. Below the header is a grey navigation bar with Home, Search, and Manage Accounts. The main content area is titled "User Profile for [redacted]" and includes a "required fields" note. There are two tabs: "User Details" (selected) and "Change Password". The "User Details" tab contains a form with fields for First Name, Last Name, Email, and Phone, each with a red asterisk indicating it's required. Below these are fields for Account Type (set to COORDINATOR) and Organization. At the bottom right of the form are "Save" and "Reset" buttons.

Labeler Data Entry User

This screenshot is similar to the one above, showing the GUDID User Profile for a Labeler. The header and navigation bar are identical. The main content area is titled "User Profile for [redacted]". The "User Details" tab is selected, showing a form with required fields for First Name, Last Name, Email, and Phone. The Account Type is set to LABELER. The "Save" and "Reset" buttons are at the bottom right.

FDA PT Code

The screenshot shows a search interface titled "Find FDA Preferred Term Code". It features a text input field with a blue arrow pointing to it from the left. To the right of the input field are three buttons: "Search", "Clear", and "Cancel". Above the input field, there's a blue arrow pointing down to the "Search" button. The top navigation bar includes Home, Search, and Manage DI, along with the FDA logo and the user name "Terrell Suggs LABELER".

The **Find FDA Preferred Term Code** functionality is available to all logged in users and will allow a search on the Global Medical Device Nomenclature (GMDN)² Preferred Term Name or GMDN Definition, to retrieve the FDA Preferred Term (PT) Code.

² Global Medical Device Nomenclature (GMDN) is a system of internationally agreed descriptors used to identify medical device products and is managed by GMDN Agency. Visit: <http://www.gmdnagency.com/default.aspx>

After entering GMDN Preferred Term Name or Definition text, and clicking the **search button**, the search results will display a list of active **FDA PT Code**, associated **GMDN Term**, and **GMDN Definition** from the database related to the keywords provided in the **search text field**.

For example, a search for the GMDN Term ‘defibrillator’ will yield the results as shown:

Find FDA Preferred Term Code

Search field: defibrillator [Search] [Clear] [Cancel]

View: 25 / 63 records, 1 / 3 page

FDA PT Code	Term	Definition
XRVN	Resuscitation trolley, equipped	A cart designed to store/transport devices and supplies used in emergency resuscitation procedures. This trolley (cart) typically consists of a shell/drawer cabinet-like structure on wheels that contains a defibrillator, electrocardiograph (ECG) monitor, pulmonary resuscitator, backboard for external cardiac compression, surgical supplies, drugs, and various other instruments and accessories necessary to initiate cardiopulmonary resuscitation (CPR).
XNDZ	External defibrillator electrode pad	A conductive medium designed to be used between the metal contact surface of an external defibrillator electrode, of the paddle-type, and the patient's skin. A defibrillator electrode pad is available in two basic designs: 1) a thickened conductive gel or polymer layer reinforced by a non-woven material; or 2) a conductive adhesive pad with a metal contact on its outer surface. This is a single-use device.
TKHP	Cardiac pulse generator test magnet	A magnetized device used to test an inhibited or triggered type of pacemaker or defibrillator, and cause an inhibited or triggered generator to revert to asynchronous operation. The device is placed on the outside of the patient's thorax over the pacemaker/defibrillator for analysis of the implanted device's function. The magnet will activate the magnet sensitive relay in the pacemaker/defibrillator and will change the function of the implanted device. It is possible to evaluate the function of the implanted device via an electrocardiograph.
RRQZ	Home automated external	A portable electronic device intended for use at home to automatically detect cardiac arrhythmias (ventricular fibrillation/pulseless ventricular tachycardia) in a sudden cardiac arrest (SCA) patient, after which it audibly/visually instructs an operator to enable it to activate defibrillation of the heart through application of electrical shocks to the

Highlighted in the picture above is the **FDA PT Code** for the GMDN Preferred Term Name “External defibrillator.electrode.pad”.

The results will show the **FDA PT Code**, the **Term** (GMDN Preferred Term Name), and the **Definition** (GMDN Definition) providing details of the active GMDN code.

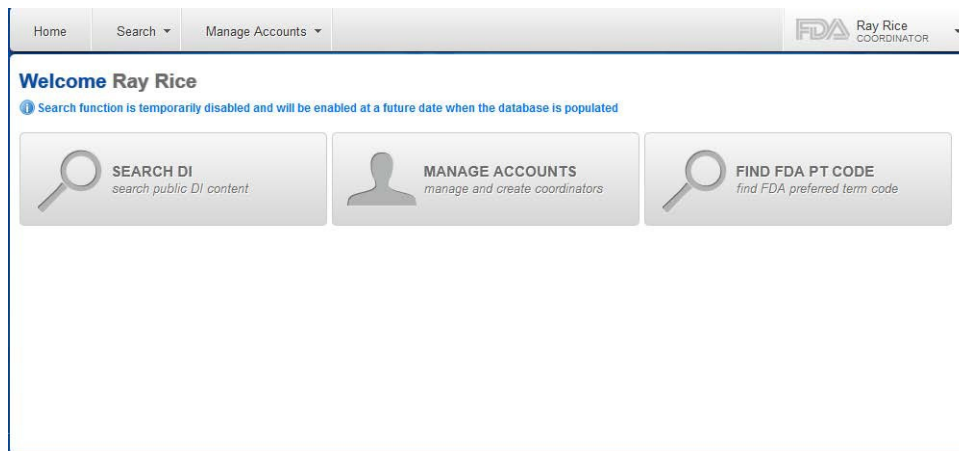


Note to system users: The GMDN is not a codeset owned by FDA. For any questions regarding GMDN Codes or how to access a full list of these terms, please contact the GMDN Agency at <https://www.gmdnagency.com/>

3.3 Coordinator

Overview of Functions available for a Coordinator Role

Coordinator Home Page



Search DI

Search DI allows a Coordinator to search for public DI records.

Note: This functionality is temporarily disabled and will be enabled when Public Search is made available.

Find FDA PT Code

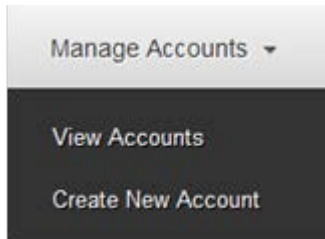


FDA PT Code allows a Coordinator to search for a GMDN Preferred Term or GMDN Definition, and retrieve the FDA assigned Preferred Term Code (See [FDA PT Code](#)) (The FDA PT Code is mapped to the GMDN code)

Manage Accounts



Manage Accounts allows a Coordinator to view and manage Labeler Data for their assigned Labeler DUNS Number.



The drop-down menu of **Manage Accounts** allows a Coordinator to navigate to **View Accounts** or **Create New Account**

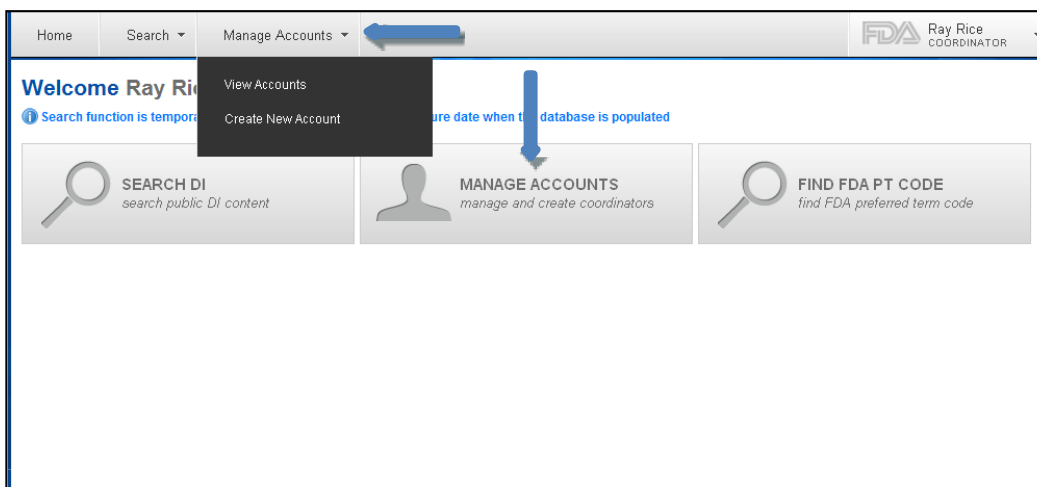
Access the Database

To begin, Login into GUDID as a Coordinator (see Subsection 2.2 for detailed information).

The home is displayed at login, see figure below.

Click the **Manage Accounts** button or select the **Manage Accounts** from the menu bar.

Note: A username and temporary password will be sent to the LDE user when the Coordinator creates an account.



Manage Accounts

Upon entry, **Manage Accounts** will display all accounts available for you in a table. You can filter for a specific account by typing in any of the fields provided – Last Name, First Name, User Name, Email, Status, Mode, etc. Enter information into the field you desire to filter by, and then click **Filter**. The results of the filter appear in the table at the bottom of the page.

Home Search Manage Accounts

Enter information. Click **Filter**. Results shown in table below.

Manage Accounts

Last Name: First Name: Username: Email: Status: Mode:

Account Type: DUNS #: Organization:

Labeler Data Entry

Filter Clear

View: 10 2/2 records

Click username to open an account.

Create new account Add New Account

Username	Last Name	First Name	Email	Account Type	Organization	Status	Mode	Password
bl_bahuss1	Bahuss1	Lili	---	Labeler Data Entry	Booz Allen & Hamilton Inc	Enabled	Activated	Reset
bl_bahuss1	LDE	P	terence.ahs.1@	Labeler Data Entry	Booz Allen & Hamilton Inc	Enabled	Activated	Reset

2/2 records, 1/1 page

Click on the *username* link to see account details.

Home Search Manage Accounts FDA Ray Rice COORDINATOR

Account Details for Suggs, Terrell

Enabled Activated Reset Password Save Reset Cancel

* required fields

General Information

Account Type: *
Labeler Data Entry

Username: * First Name: * Last Name: * Email: * Phone: *

tsuggs Terrell Suggs terrell.suggs@fda.hhs.gov 0000000000

Organization Information

Organization DUNS #: * Organization Name:

053588527 Booz Allen Hamilton Inc.

Address 1: Address 2: City: State/Province: ZIP / Postal: Country:

1 Preserve Plow Ste 200 Rockville MD 208524279 USA

Labeler DUNS

<input checked="" type="checkbox"/>	DUNS #	Organization Name	Address	City	State/Province	ZIP/Postal	Country
<input checked="" type="checkbox"/>	053588527	Booz Allen Hamilton Inc.	1 Preserve Plow Ste 200	Rockville	MD	208524279	USA

Save Reset Cancel

You can edit the account details, and then click **Save**.

Account Status and Mode

An account can have an enabled or disabled status. An enabled account is able to login in to GUDID. A disabled account cannot login to GUDID and must have the account re-enabled by a coordinator. Re-enabling the account automatically changes the user's password to a temporary password notifies the user of the change via an automated email. The temporary password must be changed before GUDID access is restored.

An account can also be inactivated or deactivated mode. The default for each account is activated mode. If an account is set to deactivated, then the account cannot access GUDID and that account cannot be recovered.

On the Manage Accounts and Account Details screen you can change the status and mode by clicking **Enabled/Disabled** and **Activated**. You can also reset the user's password which will cause the user

to receive a temporary password via email.

Create New Account

To create a new account, click Add New Account on the Manage Accounts page. On the Create New Account page, enter the required information to create a new account. When complete, click Save.

Home Search Manage Accounts

Create New Account

Complete form. Click Save.

General Information

Account Type: *
Labeler Data Entry

Username: * First Name: * Last Name: * Email: * Phone: *

Organization Information

Organization Name: *
Address 1: * Address 2: * City: * State/Province: * ZIP /Postal: * Country: *

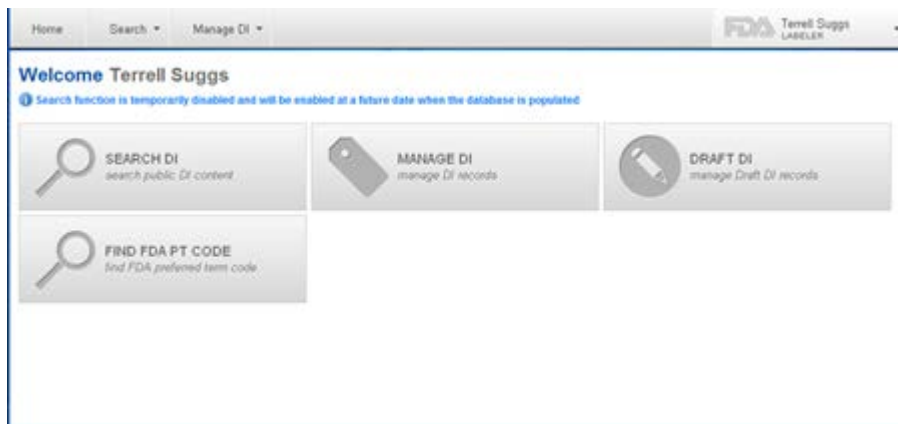
Labeler DUNS

DUNS #	Organization Name	Address	City	State/Province	ZIP/Postal	Country
077369358		12015 Lee Jackson Hwy	Fairfax	VA	220333300	USA

3.4 Labeler Data Entry (LDE) User

Overview of Functionality for Labeler Data Entry (LDE) User Role

Labeler Data Entry User Homepage



Search DI Records



Search DI allows a LDE user to search for public DI records.

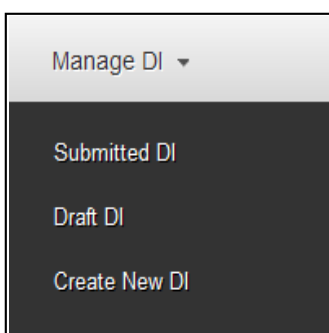
Note: This link is temporarily disabled and will be enabled when Public Search is made available.

Find FDA PT Code



Find FDA PT Code allows an LDE to search for a GMDN Preferred Term of GMDN Definition, and retrieve the FDA-assigned Preferred Term Code.

Manage DI Records (drop-down)



Manage DI allows an LDE User to create and manage DI records for their assigned Labeler DUNS numbers.

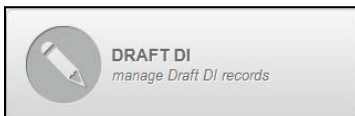
The **Manage DI** drop down allows an LDE User to navigate to **Submitted DI**, **Draft DI** or **Create NewDI** functionality.

Manage DI Records



The **Manage DI** icon will navigate the user to their Submitted DI records. This includes Published and Unpublished DI Records.

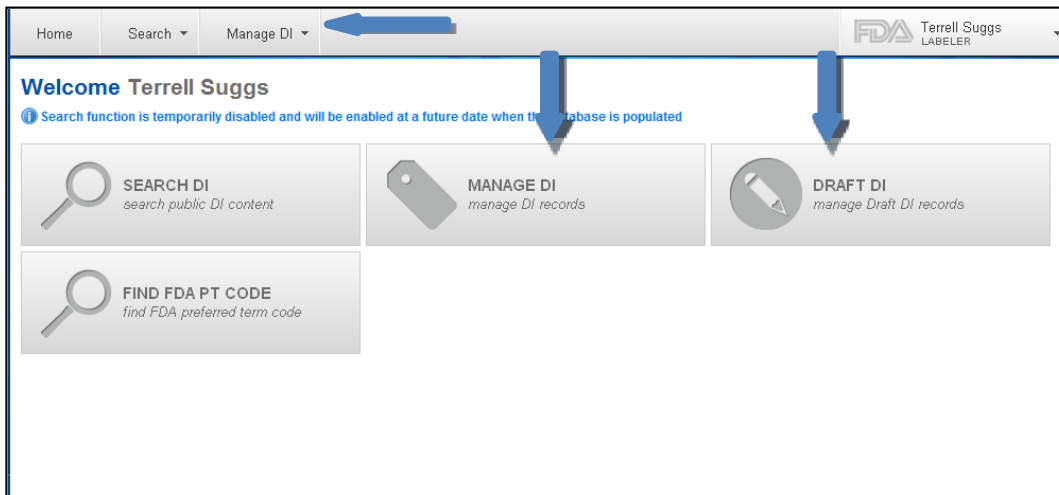
Draft DI Records



The **Draft DI** icon will navigate the user to their Draft DI records. The Draft DI records can only be viewed by the user that created the record. See examples in Appendix F.

Access the Database

To begin, login as LDE user (see Login section under Subsection 2.2 for detailed information). The home page is displayed at login, see figure below. Click the **Manage DI** and **Draft DI** buttons or **Manage DI** from the menu bar.



Manage Device Identifier (DI) Records

Upon entry, on the **Manage Device** page, published and unpublished DI records available for view will be displayed in the table. Click on a DI number to see DI record details.

You can filter for a specific DI record by typing in any of the fields provided – DI Number, Company Name, Brand Name, Version or model number, or DI Record Status (Published/Unpublished). Enter information into the field you desire to filter by and click **Filter**. Results will appear in table at bottom of screen. Click DI Number link to open DI record.

Open a published DI record from the **Manage Device** list. You will see on the top left to Device Identifier Details page that the DI record is Published.

Open an unpublished DI record from the **Manage Device** list. You will see on the top left of the Device Identifier Details page that the DI record is Unpublished.



Note to system users: *The device manufacturer cannot change a DI record status from Published to Unpublished without intervention from FDA staff.*

The screenshot displays the FDA Manage Device interface. The top section shows search filters for DI Number, Company Name, Brand Name, Version or Model Number, and DI Record Status. Below the filters is a table of DI records. The third record, with DI Number 1523412342134342, is highlighted. A callout box points to the 'Unpublished' status in the table. Below the table, the 'Device Identifier (DI) Record Details for Unpublished Record' page is shown. The status 'Unpublished' is circled in red. A tooltip indicates that the status cannot be changed from Published to Unpublished without FDA staff intervention. The details page includes fields for Issuing Agency, Primary DI Number, Device Count, Unit of Use DI Number, Labeler DURS Number, Company Name, Company Physical Address, Brand Name, Version or Model Number, and Catalog Number.

DI Number	Company Name	Brand Name	Version or Model Number	DI Record Status
02254883254882	Boyd Allen & Hummelton	Top	version	Published
1523412342134342	Boyd Allen & Hummelton	cell	cell	Unpublished
00000000000000	Boyd Allen & Hummelton	cell	cell	Deactivated

Device Identifier (DI) Record Details for Unpublished Record

Activated Unpublished View History

Device Information

Device Identifier (DI) Information

Issuing Agency: * G01 Primary DI Number: * 1523412342134342 Device Count: * 2 Unit of Use DI Number: 1523412342134342

Labeler DURS Number: * 077000000 Company Name: * Boyd Allen & Hummelton Company Physical Address: 12015 Lee Jackson Hwy, Fairfax, VA 220332200

Brand Name: * Test Version or Model Number: * version Catalog Number: 1523412342

Device Description:

Create New DI Record

When you click the New DI button, the DI Record Details screen will open up. Complete the **DI Record Details** for a new DI record. Click **Save Draft** if you have not completed the form (you must include at least the Primary Issuing Agency and Primary DI Number to save as draft). Draft DI records will appear on the Drafts DI screen for future editing (system will purge Draft DI records after 180 days from the last modified date).

Please refer to Sample DI Record for examples data entry use cases.

To submit a DI record, you must provide a valid GMDN code or an FDA Preferred Term Code (PT) Code. For assistance in understanding the GMDN description and with GMDN code assignment, we refer you to [GMDN Agency](#). To look up a valid FDA PT Code, use the **Find FDA PT Code** feature as shown in [FDA PT Code](#).

Click **Review** after you have completed the DI record. The system runs business rules on entered information to ensure all entries are valid and all required fields have values. If the DI record has errors, the user must correct the errors and click review again. Once the record is validated, the system notifies the user that the Review was successful. When the user clicks **Submit**, the DI record will be in Published or Unpublished state based on the DI Record Publish Date.

Edit Existing DI Record

Open a published DI record from the list. You will see on the top left of the screen that the DI record is **Published**. Click **Edit** at top or bottom right the page. Update the information as you desire. After editing, click Review and Submit to save changes.

Open an unpublished DI record from the list. You will see on the top left of screen that the DI record is **Unpublished**. Click **Edit** at the top or bottom of the page. Change the form as needed. After editing, click Review and Submit to save changes. Note that the Unpublished DI allows you to edit all the fields without limitation.

Home Search Manage DI FDA

Device Identifier (DI) Record Details for Published Record

Published View History [View History](#) [Copy](#) [Edit](#) [Cancel](#)

View or copy the existing DI.
Click View History for DI record history.

Click Edit to alter DI.

Device Information

Device Identifier (DI) Information

Issuing Agency: *	Primary DI Number: *	Device Count: *	Unit of Use DI Number:
GS1	02394803294802	4	44674654567456
Labeler DUNS Number: *	Company Name:	Company Physical Address:	
077369358		12015 Lee Jackson Hwy, Fairfax, VA 220333300	
Brand Name: *	Version or Model Number: *	Catalog Number:	
Test	version	12341432	

Device Description:

Commercial Distribution

DI Record Publish Date (mm/dd/yyyy): *	Commercial Distribution End Date (mm/dd/yyyy):	Commercial Distribution Status:
07/03/2013	07/24/2013	

Manage and Edit Draft DI Record

To manage draft DI records, click the **Draft DI** record button or **Draft DI** record link under the **Manage DI** dropdown. You will be returned with all of the Draft DI Records. You can choose to remove a Draft DI record permanent by clicking the **Remove** button.

To narrow the list of results, you can filter by DI number, Company Name, Brand Name, and Version or Model Number. The results of the filter appear in the table at the bottom of the page

Home Search Manage DI FDA eDMS

Manage Drafts

* required fields

DI Number: Company Name: Brand Name: Version or Model Number:

Filter Clear

View: 10 2 / 2 records, 1 / 1 page

DI Number	Company Name	Brand Name	Version or Model Number	Purge Date	Remove
09992292929998	Boehringer Ingelheim Inc.	Top	100-000000000	07/04/2013 09:56 PM	Remove
43654300004564	Boehringer Ingelheim Inc.	Top	100-000000000	06/30/2013 03:54 PM	Remove

2 / 2 records, 1 / 1 page

Click a DI number to open the DI Record Detail. You can **Edit**, **Save Draft**, **Delete Draft**, **Review** or **Cancel**. The **Save Draft** button will save the draft as long as the DI record contains a primary issuing agency and primary DI number. The **Delete Draft** button will permanently remove the draft. The **Review** button will perform validation on the DI record and if it passes, the record can be submitted. The **Cancel** button will change all changes and return the DI record back to its last saved version.

Home Search Manage DI FDA eDMS

Device Identifier (DI) Record Details for Draft Record

* required fields

Save Draft Delete Draft Review Cancel

Device Information

Device Identifier (DI) Information

Issuing Agency: * GS1 Primary DI Number: * 09992292929998 Device Count: * 4 Unit of Use DI Number: 44674654567456

Labeler DUNS Number: * 077369 Company Name: Company Physical Address: 12015 Lee Jackson Hwy, Fairfax, VA 220333300

Brand Name: * Top Version or Model Number: * 100-000000000 Catalog Number: 12341432

Device Description:

Commercial Distribution

DI Record Publish Date (mm/dd/yyyy): * 07/03/2014 Commercial Distribution End Date (mm/dd/yyyy): 07/24/2014 Commercial Distribution Status:

Copy Existing DI Record

Only Published and Unpublished DI records can be copied. To copy a DI record, go to the Manage DI page and click on the DI number you would like to copy. Click Copy to create a copy of the DI record. The copied data displays on the DI Record Details for New Record form.

Device Identifier (DI) Record Details for Published Record

Published

[View History](#)

Copy

Edit

Cancel

Device Information

Device Information

Issuing Agency: EIBCC	Primary DI Number: ekg9345hg8h45gultulwr	Device Count: *	Unit of Use: CINumber
Labeler DUNS Number: 80170941	Company Name:	Company Physical Address: 3015 Cent PI Mall, Washington, DC 200072916	
Brand Name: test	Model Number 88	Catalog Number:	



Note to system users: When working with a copied DI record (whether published or unpublished) please ensure to change all data fields to accurately capture the device information in the database.

(“Not all fields in GUDID are required to be on the label. This example is for illustrative purpose only”)



4.2 GUDID Sample Record of an Unpublished Record

4.2.1 Creating a New DI Record

The screenshot shows the GUDID web interface. The header includes the GUDID logo, 'Global Unique Device Identification Database', and links for 'About', 'UDI Website', and 'Logout'. Below the header is a navigation bar with 'Home', 'Search', and 'Manage DI' options. The main content area is titled 'Device Identifier (DI) Record Details for New Record' and includes a 'Printer Friendly' link and buttons for 'Save Draft', 'Review', and 'Cancel'. The form is divided into sections: 'Device Information' and 'Device Identifier (DI) Information'. The 'Device Identifier (DI) Information' section contains the following fields:

- Issuing Agency:** A dropdown menu with a red circle around it.
- Primary DI Number:** A text input field with a red circle around it.
- Device Count:** A text input field with a red circle around it.
- Unit of Use DI Number:** A text input field.
- Labeler DUNS Number:** A dropdown menu with a red circle around it.
- Company Name:** A text input field with the value 'SafeWay Grocery'.
- Company Physical Address:** A text input field with the value '4551 Forbes Blvd, Landover, MD 207064389'.
- Brand Name:** A text input field with the value 'CompuHyper GlobalMed Ultra Implantable' and a red circle around it.
- Version or Model Number:** A text input field with the value '123456' and a red circle around it.
- Catalog Number:** A text input field with the value '123456' and a red circle around it.
- Device Description (max 2000 characters):** A text area with the value 'A made up device for creating this record.' and a red circle around it.

Figure 2 Screenshot of GUDID interface

The fictitious medical device label in Figure 1 is used as an example to create this new DI record in GUDID. To enter Device Identifier (DI) information related to your medical device.

- Select your Issuing Agency from the drop down list. This is a required data element hence; an Issuing Agency must be selected.
- Enter Primary DI Number & Device Count. These are required data elements hence, entries must be made.
- Enter Unit of Use DI Number if applicable to your record.
- Select the appropriate Labeler DUNS Number from the drop down list. This is a required data element hence a Labeler DUNS Number must be selected.

- The Company Name and Company Physical Address is system populated through D & B Database.
- Enter Brand Name and Version or Model Number. These are required fields hence, entries must be made.
- Enter Catalog Number and Device Description.

Note that not all fields in GUDID are required. Fields that are marked with * are required data fields for GUDID. Rest of the information is required if it is available on the medical device label.

Publish date could be set in future

DI Record Publish Date (mm/dd/yyyy): * 03/31/2014

Commercial Distribution End Date (mm/dd/yyyy):

Commercial Distribution Status:

Alternative and Additional Identifiers

Direct Marking (DM)

☐ Device Subject to Direct Marking (DM), but Exempt

☐ DM DI Different from Primary DI

DM DI Number:

Secondary DI

[Add Secondary DI](#)

Issuing Agency	Secondary DI Number	Action
No secondary device identifiers currently defined		

Package DI

[Add Package DI](#)

Package DI Number	Quantity per Package	Contains DI Package	Package Type	Package Discontinue Date	Package Status	Action
No package device identifiers currently defined						

Figure 3 Screenshot of GUDID Interface

As you scroll down in the New Record window you will be able to enter Commercial distribution information of the device.

- Select or enter DI Record Publish date in mm/dd/yyyy format. This is a required data element hence; DI Publish Record Date must be selected.
- Select or enter Commercial Distribution End Date in mm/dd/yyyy format.
- Commercial distribution status field is system populated based on your entries in DI Record Publish date and Commercial Distribution End Date.

In the Alternative and Additional Identifiers section enter the following Direct Marking (DM) information if it applicable to your medical device for which the record is being created.

- Check the “Device Subject to Direct Marking (DM), but Exempt”
- Check “DM DI Different from Primary DI”. If the “DM DI Different from Primary DI” is checked then enter the DM DI Number.

For entering Secondary DI number

- Click on the Add Secondary DI
- Select the Issuing Agency from the drop down list
- Enter Secondary DI Number
- Action allows user to make changes to Secondary DI.

For entering multiple levels of packaging

- Click on Add Package DI
- Enter Package DI Number
- Enter Quantity per Package
- Enter Contains DI Package
- Enter Package Type
- Enter Package Discontinue Date (if applicable)
- Enter Package Status
- Action button allow users to edit the information

Customer Contact		
		+ Add Customer Contact
Customer Contact Phone	Customer Contact Email	Action
8005551234	xxx@xx.xx	
+15555551234	xxx@xx.xx	

For entering Customer Contact information click on Add Customer Contact

- Enter Customer Contact Phone. If there is no phone number please enter 999-999-9999
- Enter Customer Contact Email. If there is no email please enter [xxx@xx.xx](#)
- Action allows user to make changes to Customer contact.

When checkboxes are not checked value is set to “No”

Device Status

☐ Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)
 ☐ Kit
 ☐ Combination Product

Premarket *

☐ Device Exempt from Premarket Submission
 [+ Add Premarket Submission Number](#)

FDA Premarket Submission Number	Supplement Number	Action
14090030	0	

FDA Listing *

[+ Add Listing](#)

FDA Listing Number	Action
14090030	

FDA Product Code *

[+ Add Product Code](#)

Product Code	Product Code Name	Action
07	Oil, Clearing	

GMDN *

[+ Add GMDN](#)

Code	Name	Definition	Action
	Acidfast-agar culture medium IVD		

Enter Premarket Submission Number and Supplement number which are used to obtain approval for the version or model number of the device for which this record is being created.

Figure 4 Screenshot of GUDID interface

In Device Status section

- Check if the device is Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)
- Check if the device is a Kit
- Check if the device is a Combination Product

For entering Premarket information

- Click on Add Premarket Submission Number
- Check if the device is exempt from Premarket Submission
- Enter FDA Premarket Submission Number and the Supplement Number
- Action button allow users edit the information

For entering FDA Product Code

- Click on Add Product Code
- Enter FDA Product Code
- Product Code Name is system populated from the FDA Premarket Submission database.

-Action button allow users to edit the information

For entering FDA Listing Number

-Click on Add Listing Number

-Enter a valid and relevant FDA Listing Number

-Action button allow users to edit the information

For entering GMDN Code

-Click on Add GMDN Code

-Enter GMDN Code

-Name will be automatically updated by the system

-Action button allow users to edit the information

Device Characteristics

For Single-Use: * Yes

Production Identifier(s) on Label

Lot or Batch Number: * Yes

Manufacturing Date: * No

Serial Number: * No

Expiration Date: * Yes

Donation Identification Number: * No

Prescription Status

☐ Prescription Use (Rx)

☐ Over the Counter (OTC)

Latex Information

Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437): *

No

☐ Device labeled as "Not made with natural rubber latex"

MRI Safety

What MRI safety information does the labeling contain?: *

Labeling does not contain MRI Safety Information

Clinically Relevant Size

[Add Size](#)

Size Type Text	Action
Length: 8 Millimeter	
Length: 2.25 Millimeter	

Figure 5 Screenshot of GUDID interface

In Device Characteristics section

-Select the appropriate value from the drop down list for whether the device is intended for single use. This is a required field and hence, a value must be selected.

-Enter the Production Identifiers on the Label and make appropriate selections from the drop down list for Lot or Batch number, Manufacturing Date, Serial Number, Expiration Date and Donation Identification Number. All these fields are required and hence, a value must be selected.

- Select a value from the drop down list for Device required to be labeled as containing natural rubber latex or dry natural rubber (21CFR 801.437). This is a required field and hence, a value must be selected.
- Check if the Device is labeled as “Not made with natural rubber latex”
- Check if the device requires Prescription Use (Rx)
- Check if the device is available Over the Counter
- Select a value from the drop down list as an answer for the question “What MRI safety information does the labeling contain? This is a required field and hence, a value must be selected.
- For adding clinically relevant
- Click on the Add size button.
- Action button allow users edit the information

Storage and Handling

[+ Add Storage and Handling](#)

Storage and Handling	Action
Storage Environment Temperature: less than 45 Degrees Celsius	

Sterilization

Device Packaged as Sterile: * **Yes** ▼

Requires Sterilization Prior to Use: * No ▼

[+ Add Sterilization Method](#)

Sterilization Method	Action
No sterilization method currently defined	

☒ Activated
 ☐ **Unpublished**
[View History](#)
[Printer Friendly](#)

[Review](#)
[Cancel](#)

Figure 6 Screenshot of GUDID interface

For entering Storage and Handling information

- Click on the Add Storage and Handling button
- Action button allow users edit the information

Enter information related to Sterilization

- Enter/Select the appropriate entry from the drop down list for Device Packaged as Sterile. This is a required element hence, a value must be selected.

- Enter/Select the appropriate entry from the drop down list for Requires Sterilization Prior to Use. This is a required element hence, a value must be selected.
- Enter a sterilization Method by clicking on the Add Sterilization Method.
- Action button allow users to edit the information

Currently, the DI record is in an unpublished state

- Review checks whether the record has met all the system and business rules
- Cancel allows users to exit the screen without saving the record.



***Note to system users: Unpublished records can be edited unlimited number of times.
However, after each edit records need to meet all the business rules as defined in the system.
The system will automatically check for the publish date and move the records to published DI
state on the day when publish date = today.***